JUL 2 0 2000

K001376

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

CONTACT PERSON: Tracy J. Bickel

DEVICE NAME: Ti-MAX Protrusio Cage

CLASSIFICATION NAME: Hip joint metal/polymer semi-constrained cemented prosthesis (88.3350)

INTENDED USE: The Protrusio implants are intended for use in reconstruction of the hip joint due to disease, deformity or trauma. The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery. The device is a single use implant. The Protrusio Cage is to be used in conjunction with any commercially available polyethylene acetabular cup.

DEVICE DESCRIPTION: This series of four anatomic protrusio cages comes in sizes 52mm-64mm in four millimeter increments. Each cage has two iliac flanges positioned superiorly and one ischial flange positioned inferiorly that provide supplemental screw fixation holes for attachment to the ilium and ischium. These cages, once positioned in the acetabulum and attached to the ilim and ischium, provide structural integrity to an otherwise structurally compromised joint. The improved acetabular construct gained by attaching the device provides a much better site for installation of the functional acetabular bearing surface. The material, CP Titanium, was chosen so that the flanges can be bent intra-operatively in order to match the device to the geometry of the pelvis.

In cases where bony defects or voids exist, optional augments with a grit blast finish can be utilized to help provide additional structural support. The augments are attached to the cage by means of a locking screw.

This device is intended for cemented application.

POTENTIAL RISKS:

The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Fracture of the component	Bone fracture
Cardiovascular disorders	Hematoma
Implant loosening/migration	Blood vessel damage
Soft tissue imbalance	Nerve damage

Deformity of the joint	Excessive wear
Tissue growth failure	Infection
Delayed wound healing	Dislocation
Metal sensitivity	Breakdown of the porous surface

SUBSTANTIAL EQUIVALENCE:

Direct comparison was made with the following predicates:

1) Modular Protrusio Cage (K990032): Biomet, Inc.
2) Recovery Protrusio Cage (971890): Biomet, Inc.
3) Modular Acetabular Reconstructive System (M.A.R.S.) (K911718): Biomet, Inc.

All aforementioned products are manufactured in Warsaw, IN.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2000

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.,
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K001376
Trade Name: Ti-Max Protrusio Cage
Regulatory Class: II
Product Code: JDI
Dated: April 28, 2000
Received: May 1, 2000

Dear Ms. Bickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001376
Device Name: Recovery Protrusio Cage
Indications for Use:

The Protrusio implants are intended for use in reconstruction of the hip joint due to disease, deformity or trauma. The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery. The device is a single use implant. The Protrusio Cage is to be used in conjunction with any commercially available polyethylene acetabular cup.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____
(Optional Format 1-2-96)

Donna R. Bachman
(Division Sign-Off)
Restorative Devices
510(k) Number K001376